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Alma Woodberry
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gary Ruvkun et al.	Art Unit:	1632
Serial No.:	08/908,453	Examiner:	Ram R. Shukla
Filed:	August 7, 1997	Customer No.:	21559
Title:	AGE-1 POLYPEPTIDES AND RELATED MOLECULES AND METHODS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO EXAMINER'S ACTION

In reply to the Office action that was mailed in connection with the above-captioned patent application on July 8, 2003, applicants submit the following remarks.

REMARKS

Claims 8, 10-13, 15, 16, 19, and 20 are under examination in the present case. Claims 8, 10, and 11 are rejected under 35 U.S.C. § 102(a) and claims 8, 10-13, 15, 16, and 19 and 20 are rejected under 35 U.S.C. § 103. The rejections are addressed below.

Rejections under 35 U.S.C. § 102(a)

Anticipation

Claims 8, 10, and 11 are rejected under 35 U.S.C. § 102(a) as being anticipated by Swinburne (GenBank Accession No. Z66519). Claims 8, 10, and 11 are directed to purified and isolated DNA encoding an AGE-1 polypeptide (SEQ ID NO: 1). The invention is based on applicants' identification of the nucleic acid sequence encoding the AGE-1 polypeptide.

The Examiner cites Accession No. Z66519, 27 October 1995, and asserts that Swinburne discloses the amino acid sequence of SEQ ID NO:1. Applicants respectfully disagree.

Applicants note that the nucleic acid sequence of cosmid B0334 (Gene Bank Accession No. Z66519) has been continually updated since it first became available in October 1995, as evidenced by Exhibit A, which provides a sequence revision history. In Exhibit B, applicants provide the version of Gene Bank Accession No. Z66519 available as of July 29, 1996, a deposit made just prior to the filing of applicants' priority document (U.S.S.N. 60/023,382). As shown in Exhibit B, at page 4, as of July 29, 1996, the polypeptide product of B0334.8, which encodes AGE-1 (as evidenced in Exhibit C,

under the heading "Definition"), contained just seventy-six amino acids. In contrast, the AGE-1 polypeptide sequence (SEQ ID NO:1) contains one thousand one hundred forty-six amino acids. Thus, contrary to the Office's assertion, the amino acid sequence disclosed by Swinburne Z55419 [gi:1044812] clearly does *not* contain SEQ ID NO:1.

In fact, contrary to the Office's assertion, the nucleic acid sequence of AGE-1 was *not* publicly available at the time applicants patent application was filed. This point is made clear in applicants' specification at page 20, lines 1-7, where applicants state:

> The *C. elegans* Genome Project has sequenced cosmid B0334. Analysis of the DNA sequence in the 4 kb region that detected the *age-1(mg55)* breakpoint revealed two putative exons that showed strong sequence identity with the last 88 amino acids of mammalian phosphatidylinositol 3-kinase (PI 3-kinase)p110 catalytic subunit. *The region to the right of B0334 expected to contain the rest of age-1 was not cloned in cosmids or phage by the C. elegans genome project* (emphasis added).

In fact, applicants were the first to obtain the *age-1* nucleic acid and amino acid sequences, as evidenced by applicants' specification at page 20, lines 7-17.

> *We isolated genomic phage and cDNA clones extending to the right from B0334 and used anchored polymerase chain reaction (PCR) of reverse transcribed RNA to isolate and determine the sequence of the coding region of age-1.* To confirm the splicing pattern of *age-1,* reverse transcription PCR (RTPCR) was used in conjunction with genomic sequencing of predicted splice junctions. The sequence predicted by cDNA clones and anchored PCR was further confirmed by sequencing genomic fragments corresponding to the predicted coding sequence. Because three independent cDNA clones end within 30 base pairs of each other and because these encode a protein coextensive with mammalian p110 (see below), we concluded that the assembled *age-1* cDNA was likely to be complete. The nucleic acid sequence of the *C. elegans age-1* cDNA is shown in Figure 4 (emphasis added).

If the *age-1* nucleic acid sequence were publicly available, applicants would not have gone to the trouble of cloning and sequencing the gene. As evidenced by applicants specification and the version of the cosmid sequence available at the time applicants' application was filed, Swinburne fails to disclose a nucleic acid sequence encoding SEQ ID NO:1, as required by claims 8, 10, and 11. Thus, the anticipation rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 8, 10-13, 15, 16, 19, and 20, which feature compositions and methods requiring the AGE-1 amino acid sequence (SEQ ID NO:1), are rejected under 35 U.S.C. § 103 as obvious over Swinburne (Gene Bank Accession No. Z66519) in view of Johnson et al. (Genetica 91:65-77, 1993). The Examiner states:

> . . . it would have been obvious for an artisan of skill to express the DNA of Swinburne in a cell and express the protein in a cell, isolate the protein and study its function or practice method of identifying compounds that decrease the expression of Age-1 by following the method of Johnson et al and routine cell culture methods. An artisan of skill would have been motivated to express Age-1 in a cell, isolated Age-1 protein and tested its activity because Swinburne identified putative functional domain. Additionally, an artisan would have been motivated to practice the screening methods for identifying compounds that decrease Age-1 activity because Johnson et al teaches that molecular cloning and characterization of Age-1 locus will provide significant insights into the molecular basis of senescence. (Office Action mailed July 8, 2003, page 4, first paragraph.)

This rejection is respectfully traversed.

Swinburne

As detailed above, and evidenced by Exhibit B, Swinburne fails to disclose SEQ ID NO:1; fails to disclose the nucleic acid sequence encoding SEQ ID NO:1; fails to identify *any* functional domain of AGE-1; and even fails to disclose that the *age-1* gene was present on B0334.

Johnson

Johnson fails to remedy the deficiencies of Swinburne. Johnson merely describes the effects of *age-1* on lifespan and maps *age-1* to chromosome II. Swinburne and Johnson cannot teach or suggest what they themselves failed to recognize. None of the references cited by the Office provides the skilled artisan with the requisite motivation or expectation of success required to obtain a nucleic acid sequence encoding SEQ ID NO:1, to express it in a cell, and to study its function.

Applicants were the first to genetically map, clone, and sequence *age-1* as evidenced by applicants' specification. Applicants carried out three-factor mapping, deficiency mapping, physical mapping, breakpoint analysis, and anchored polymerase chain reaction of reverse transcribed RNA to isolate and sequence the *age-1* coding region (pages 19-21, Figures 2A, 2B, 2C). The *age-1* nucleic acid and amino acid sequences obtained by applicants are shown in Figures 3. Applicants were the first to molecularly characterize mutant alleles of *age-1* (page 20, line 24, to page 21, line 7); were the first to appreciate that *age-1* encodes a phosphatidylinositol 3-kinase (page 21, line 3, to page 22, line 25); and were the first to appreciate that a decrease in AGE-1

activity would increase lifespan (page 22, line 26, to page 23, line 23). The references cited by the Office uniformly fail to recognize these key insights and therefore fail to support the Office's obviousness rejection. Thus, this rejection should also be withdrawn.

CONCLUSION

Applicants submit that this case is in condition for allowance, and such action is respectfully requested. If the Office does not concur, a telephonic interview with the undersigned is hereby requested.

Enclosed is a Petition to extend the period for replying to the Office action for two months, to and including November 12, 2003, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 12 November 2003

Karen L. Elbing, Ph.D.
Reg. No. 35,238

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Telephone: 617-428-0200
Facsimile: 617-428-7045

EXHIBIT A

NCBI

Sequence Revision History

PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Book

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LocusLink

Clusters of orthologous groups

Protein reviews on the web

Revision history for Z66519

GI	Version	Update Date	Status	I	II
18369669	2	Oct 23 2003 11:29	Live	◉	○
18369669	2	Sep 25 2003 12:08	Dead	○	◉
18369669	2	Aug 11 2003 11:26	Dead	○	○
18369669	2	Jul 28 2003 9:44	Dead	○	○
18369669	2	May 22 2003 11:12	Dead	○	○
18369669	2	Apr 27 2003 11:09	Dead	○	○
18369669	2	Jan 14 2003 11:12	Dead	○	○
18369669	2	Dec 16 2002 12:32	Dead	○	○
18369669	2	Nov 14 2002 11:10	Dead	○	○
18369669	2	Nov 8 2002 11:37	Dead	○	○
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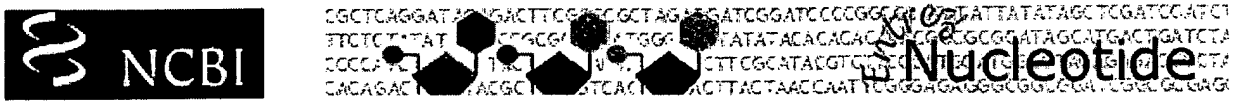
Accession Z66519 was first seen at NCBI on Oct 30 1995 2:27

EXHIBIT B



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☐ **1:** Z66519[gi:1044812] This record was replaced or removed. See revision history for details.

```
LOCUS       CEB0334                41812 bp    DNA     linear   INV 27-JUL-1996
DEFINITION  Caenorhabditis elegans cosmid B0334.
ACCESSION   Z66519
VERSION     Z66519  GI:1044812
KEYWORDS    Gonadotrophin-releasing hormone receptor like protein; oxalyl-CoA
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            protein; Yeast hypothetical protein L8167.12 like protein.
SOURCE      Caenorhabditis elegans
  ORGANISM  Caenorhabditis elegans
            Eukaryotae; mitochondrial eukaryotes; Metazoa; Nematoda;
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            Rhabditidae; Caenorhabditis.
REFERENCE   1  (bases 1 to 41812)
  AUTHORS   Swinburne,J.
  TITLE     Direct Submission
  JOURNAL   Submitted (26-OCT-1995) Nematode Sequencing Project, Sanger Centre,
            Hinxton, Cambridge CB10 1RQ, England and Department of Genetics,
            Washington University, St. Louis, MO 63110, USA. E-mail:
            jes@sanger.ac.uk or rw@nematode.wustl.edu
REFERENCE   2  (bases 1 to 41812)
  AUTHORS   Wilson,R., Ainscough,R., Anderson,K., Baynes,C., Berks,M.,
            Bonfield,J., Burton,J., Connell,M., Copsey,T., Cooper,J.,
            Coulson,A., Craxton,M., Dear,S., Du,Z., Durbin,R., Favello,A.,
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            Johnston,L., Jones,M., Kershaw,J., Kirsten,J., Laister,N.,
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            O'Callaghan,M., Parsons,J., Percy,C., Rifken,L., Roopra,A.,
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            Vaughan,K., Waterston,R., Watson,A., Weinstock,L.,
            Wilkinson-Sproat,J. and Wohldman,P.
  TITLE     2.2 Mb of contiguous nucleotide sequence from chromosome III of C.
            elegans
  JOURNAL   Nature 368 (6466), 32-38 (1994)
  MEDLINE   94150718
COMMENT     Current sequence finishing criteria for the C. elegans genome
            sequencing consortium are that all bases are either sequenced
            unambiguously on both strands, or on a single strand with both a
            dye primer and dye terminator reaction, from distinct subclones.
            Exceptions are indicated by an explicit note.
            IMPORTANT:  This sequence is NOT necessarily the entire insert of
            clone B0334.  It may be shorter because we only sequence
            overlapping sections once, or longer because we arrange for a small
            overlap between neighbouring submissions.
            The true left end of clone B0334 is at 1 in this sequence. The true
            right end of clone B0334 is at 41812 in this sequence. The true
            right end of clone W02B12 is at 4181 in this sequence. Coding
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sequences below are predicted from computer analysis, using the program Genefinder (P. Green, ms in preparation), and other available information.

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EXHIBIT C

1: CAA91377. C. elegans AGE-1 ...[gi:6018364]

LOCUS CAA91377 1146 aa linear INV 23-OCT-2003
DEFINITION C. elegans AGE-1 protein (corresponding sequence B0334.8) [Caenorhabditis elegans].
ACCESSION CAA91377
VERSION CAA91377.2 GI:6018364
DBSOURCE embl locus CEY62F5A, accession AL110499.1
embl locus CEB0334, accession Z66519.2
KEYWORDS .
SOURCE Caenorhabditis elegans
ORGANISM Caenorhabditis elegans
Eukaryota; Metazoa; Nematoda; Chromadorea; Rhabditida; Rhabditoidea; Rhabditidae; Peloderinae; Caenorhabditis.
REFERENCE 1
AUTHORS none.
TITLE Genome sequence of the nematode C. elegans: a platform for investigating biology. The C. elegans Sequencing Consortium
JOURNAL Science 282 (5396), 2012-2018 (1998)
MEDLINE 99069613
PUBMED 9851916
REMARK The C.elegans Sequencing Consortium.
REFERENCE 2 (residues 1 to 1146)
AUTHORS Swinburne,J.
TITLE Direct Submission
JOURNAL Submitted (27-OCT-1995) Nematode Sequencing Project, Sanger Institute, Hinxton, Cambridge CB10 1SA, England and Department of Genetics, Washington University, St. Louis, MO 63110, USA. E-mail: jes@sanger.ac.uk or rw@nematode.wustl.edu
COMMENT On Oct 11, 1999 this sequence version replaced gi:3873748.
Coding sequences below are predicted from computer analysis, using predictions from Genefinder (P. Green, U. Washington), and other available information.
Current sequence finishing criteria for the C. elegans genome sequencing consortium are that all bases are either sequenced unambiguously on both strands, or on a single strand with both a dye primer and dye terminator reaction, from distinct subclones. Exceptions are indicated by an explicit note.
This sequence is the entire insert of clone B0334. The true right end of clone W02B12 is at 4181 in this sequence. The start of this sequence (1..104) overlaps with the end of sequence Z66521.
The end of this sequence (41657..41812) overlaps with the start of sequence AL110499.
For a graphical representation of this sequence and its analysis see:- http://wormbase.sanger.ac.uk/perl/ace/elegans/seq/sequence?name=B0334
IMPORTANT: This sequence is NOT necessarily the entire insert of the specified clone. It may be shorter because we only sequence overlapping sections once, or longer because we arrange for a small

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            overlap between neighbouring submissions.
            [020104 dl] Sequence correction based on Thierry-Mieg EST analysis.
FEATURES             Location/Qualifiers
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                     complement(AL110499.1:2872..3132),
                     complement(AL110499.1:2446..2820),
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                     complement(Z66519.2:41436..41568),
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                     family, accessory domain (PIK domain)), Score=41.6,
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